UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

MARILYN KUHN, Plaintiff, v. BIOMET ORTHOPEDICS, BIOMET, INC., and BIOMET MANUFACTURING, CORP. Defendants.	Civil Case No. MDL Case No. 3:12-md-2391 **COMPLAINT** **JURY TRIAL DEMANDED**

INTRODUCTION

This is a product liability case involving a defective hip implant system. Plaintiff had a Biomet M2a Magnum Metal-on-Metal Hip System ("M2a Magnum Hip System") implanted in Plaintiff's right hip. The M2a Hip contains defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the implant to fail and the surrounding tissue and bone to die. As a result of these defects, Plaintiff's M2a Magnum Hip System failed, causing severe pain and suffering.

VENUE STATEMENT

1. Venue of this case is appropriate in the United States District Court for the Southern District of Ohio. Plaintiff states that but for the Order permitting direct filing into the Northern District of Indiana, Plaintiff would have filed in the United States District Court for the

Southern District of Ohio. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

PARTIES AND JURISDICTION

2. Plaintiff Marilyn Kuhn is a resident and citizen of Ohio, and claims damages as set forth below. Plaintiff currently resides in Hopewell, Muskingum County, Ohio.

3. Defendant Biomet Orthopedics, LLC is a limited liability company organized and existing under the laws of the State of Indiana with its primary place of business in Warsaw, Indiana 46582-6989. Additionally, upon information and belief, Biomet Orthopedics, LLC's members all reside in Indiana, and are thus citizens of Indiana. Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit. Biomet Orthopedics, LLC is wholly-owned by Biomet U.S. Reconstruction, LLC, which is wholly-owned by Biomet, Inc.

4. Defendant Biomet, Inc. is a corporation organized and existing under the laws of the State of Indiana with its primary place of business and corporate headquarters located at 56 East Bell Drive, Warsaw, Indiana 46582-6989. Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit. Biomet, Inc. is the parent company of Biomet U.S. Reconstruction, LLC, which wholly-owns Biomet Orthopedics, LLC.

5. At all times material hereto, Biomet Orthopedics, LLC and Biomet, Inc. developed, designed, tested, manufactured, distributed, marketed, and sold the M2A Magnum Hip System. Defendants' products, including the M2A Magnum Hip System, are sold throughout the world, including within the State of Ohio.

6. Plaintiff is claiming more than $75,000 in damages, exclusive of interest and costs, and federal jurisdiction is supported by 28 U.S.C. § 1332.

BACKGROUND

A. The M2A Magnum Hip System is Defective and Was Not Adequately Tested.

7. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

8. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joining when it is placed inside the polyethylene liner and acetabular shell.

9. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's M2a Magnum Hip System has a critical difference: it is a monoblock system which does not have an acetabular liner. Instead, the M2a Magnum Hip System forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective design for the M2a Magnum Hip System, hundreds of patients, including Robert Davis, have been forced to undergo surgeries to replace the failed hip implants.

10. The M2a Magnum Hip System suffers from a design or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adjuster. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. The rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

11. The design of the M2a Magnum Hip System was not sufficiently tested by Biomet, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

12. On numerous occasions, Biomet met or communicated with orthopedic surgeons around the country to promote the M2a Magnum Hip System. At some or all of these meetings, a representative or representatives of Biomet was present. During these meetings or communications, Biomet assured the orthopedic surgeons that the M2a Magnum Hip System was safe, was the best product on the market, and had an excellent track record and a low and acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip System even after they became aware of the numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold the M2a Magnum Hip System to Plaintiff After It Knew It Was Defective, That It Had Injured Others, and That It Would Injure Her.

13. It wasn't long after Biomet launched the M2a Magnum Hip System that reports of failures began flooding into Biomet. For example, in August 2004, Biomet received a complaint

that a patient had to undergo a surgery to remove and replace an M2a Magnum Hip System because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

14. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum Hip System failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. More than 350 reports have been filed with the FDA.

15. By the time Biomet sold the M2a Magnum Hip System to Plaintiff, Biomet was fully aware that the M2a Magnum Hip System was defective and other patients already had been injured by that defect. Based on this information, Biomet should have recalled the M2a Magnum Hip System before it was sold to Plaintiff or at a minimum Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

16. Despite its knowledge that the M2a Magnum Hip System had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Biomet continues to sell the defective M2a Magnum Hip System. In so doing, Biomet actively concealed the known defect from doctors and patients – including Plaintiff and Plaintiff's doctor – and misrepresented that the M2a Magnum Hip System was a safe and effective medical device.

17. As numerous failures of the M2a Magnum Hip Implant were reported to Biomet, it continued to actively promote, market and defend the defective products. For example, Biomet published marketing brochures, touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum Hip System. These brochures were given to doctors around the world to encourage them to use the M2a Magnum Hip System.

18. Despite its knowledge that the M2a Magnum Hip System was defective, Biomet also made several false misrepresentations about specific design elements of the M2a Magnum Hip System that they claimed made it superior to other more safe hip implants on the market. For example, Biomet said:

> "The M2a MagnumTM Large Metal Articulating System offers optimal joint mechanic restoration and ultra low-wear rate in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

19. Biomet's reason to conceal the defect in its M2a Magnum System is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum is one of its most profitable products. During the time period relevant to this Complaint, Biomet's management was attempting to make Biomet seem appealing to investors, and it ultimately was purchased by a private equity firm in 2007 for $10 billion. Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the M2a Magnum Hip System despite the fact that it knew the product was still defective. To this day, Biomet continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff's M2a Magnum Hip System Was Defective and Failed, Causing Substantial Pain and Suffering.

20. On August 27, 2008, Marilyn Kuhn underwent a surgical procedure to implant the M2a Magnum Hip System in her right hip. By this time, numerous reports of adverse events associated with the M2a Magnum had been filed with the FDA and Biomet knew that the

product was defective. But, Biomet refused to disclose that information to Plaintiff, Plaintiff's physicians, or the public. Instead, Biomet misrepresented to Plaintiff and Plaintiff's orthopedic surgeon that the M2a Magnum Hip System was safe and effective. In reliance on these representations, Plaintiff's orthopedic surgeon made the decision to use the M2a Magnum Hip System. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System in Plaintiff's hip replacement surgery.

21. As a result of the defective design, manufacture and composition of the M2a Magnum Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant failed, causing a revision surgery on June 30, 2015, severe pain, discomfort, difficulty walking and required continued medical care.

22. As a direct and proximate result of the failure of her defective M2a Magnum Hip System and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000 jurisdictional minimum of this Court.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – Against All Defendants

23. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

24. Biomet designed, manufactured, promoted, distributed, marketed, and sold the M2a Magnum Hip System.

25. At all times material hereto, the M2a Magnum Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff and Plaintiff's physician, without substantial change in the condition in which it was sold.

26. At all times material hereto, the M2a Magnum Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the M2a Magnum Hip System contained manufacturing defects, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not grow properly into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

b. When placed in the stream of commerce, the M2a Magnum Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

c. The M2a Magnum Hip System was insufficiently tested; and

d. The M2a Magnum Hip System was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff or Plaintiff's physicians of the full nature or extent of the risks associated with Plaintiff's use.

27. Biomet knew or should have known of the dangers associated with the use of the M2a Magnum Hip System, as well as the defective nature of the M2a Magnum Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the M2a Magnum Hip System so as to maximize sales and profits at the expense of the public

health and safety. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the M2a Magnum Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

28. Plaintiff and Plaintiff's doctor used the M2a Magnum Hip System as directed for its intended purpose.

29. At all times herein mentions, the M2a Magnum Hip System was defective, and Biomet knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Plaintiff nor Plaintiff's physicians knew or had reason to know of the existence of the aforementioned defects. Neither Plaintiff nor Plaintiff's physicians could have discovered the defects in the M2a Magnum Hip System through the exercise of reasonable care.

30. The M2a Magnum Hip System had not been materially altered or modified prior to its implantation in Plaintiff.

31. As a direct and proximate result of the failure of the defective M2a Magnum Hip System, Plaintiff suffered the injuries and damages described herein.

COUNT II
NEGLIGENCE - Against All Defendants

32. Plaintiffs incorporate all the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

33. At all times herein mentioned Biomet had a duty to exercise reasonable care in the design, manufacture, testing inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

34. Biomet maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System.

35. Biomet maliciously, recklessly and/or negligently made misrepresentations about the safety and effectiveness of the M2a Magnum Hip System to Plaintiff and Plaintiff's orthopedic surgeon. In reliance on these misrepresentations, Plaintiff's orthopedic surgeon decided to use the M2a Magnum Hip Implant in Plaintiff's surgery. If it was not for the misrepresentations by Biomet, Plaintiff's orthopedic surgeon would have not used the M2a Magnum Hip System in Plaintiff's surgery.

36. Biomet maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Plaintiff and Plaintiff's physicians as to the risks of the M2a Magnum Hip System.

37. Biomet maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the M2a Magnum Hip System when they knew or should have known of said risks.

38. Biomet's conduct was done in conscious disregard for the rights and safety of consumers such as Plaintiff.

39. As a result of Biomet's wrongful conduct, Plaintiff suffered injuries and damages alleged herein.

COUNT III
BREACH OF IMPLIED WARRANTIES – Against All Defendants

40. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

41. Prior to the time that the M2a Magnum Hip System was used by Plaintiff, Biomet impliedly warranted to Plaintiff and Plaintiff's physicians that the M2a Magnum Hip System was of merchantable quality and safe and fit for the use for which it was intended.

42. Plaintiff and Plaintiff's physicians were and are unskilled in the research, design and manufacture of the M2a Magnum Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Biomet in using the M2a Magnum Hip System.

43. The M2a Magnum Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Biomet, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

44. Biomet, by selling, delivering and/or distributing the defective M2a Magnum Hip System to Plaintiff, breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

45. As a result of the aforementioned breach of implied warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT IV
BREACH OF EXPRESS WARRANTY – Against All Defendants

46. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

47. At all times herein mentioned, Biomet expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Biomet or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials

intended for physicians, medical patients and the general public, that the aforementioned M2a Magnum Hip System was safe, effective, fit and proper for its intended use.

48. In utilizing the aforementioned M2a Magnum Hip System, Plaintiff and Plaintiff's physician relied on the skill, judgment, representations and foregoing express warranties of Biomet.

49. Said warranties and representations were false in that the aforementioned M2a Magnum Hip System was not safe and was unfit for the uses for which it was intended.

50. As a result of the foregoing breach of express warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT V
FAILURE TO WARN – Against All Defendants

51. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

52. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the M2a Magnum Hip System, and in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the M2a Magnum Hip System.

53. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's physician, of the true risks of the M2a Magnum Hip System, including that the M2a Magnum Hip System suffers defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral

head, and the taper sleeve, which in turn causes the implant to fail and the surrounding tissue and bone to die. As a result of these defects, Plaintiff's M2a Magnum Hip System failed in Plaintiff's body, causing tissue and bone destruction and severe pain and suffering.

54. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of M2a Magnum Hip Systems. Had Defendants done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used M2a Magnum Hip Systems. Moreover, no consumer, including Plaintiff, would have purchased and/or used M2a Magnum Hip Systems.

55. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of M2a Magnum Hip Systems. Had Defendants done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the M2a Magnum Hip Systems, without causing serious pain and injury to patients, including Plaintiff.

56. M2a Magnum Hip Systems, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, were defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between M2a Magnum Hip Systems and excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the implant to fail and the surrounding tissue and bone to die, causing serious injury and pain. Defendants failed to provide adequate warnings to health care professionals and the unknowing public, including Plaintiff, and continued to aggressively promote M2a Magnum Hip Systems.

57. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

58. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent economic and non-economic injuries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For compensatory damages requested and according to proof,

Including:

a. past, present and future pain and suffering;

b. past, present and future medical expenses;

c. loss of earnings/earnings capacity; and

d. loss of enjoyment of life.

2. For punitive or exemplary damages;

3. For all applicable statutory damages of the state whose laws will govern this action;

4. For prejudgment and post judgment interest and the costs of suit; and

5. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

Date: April 12, 2017

Respectfully Submitted,

WAGSTAFF & CARTMELL LLP

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